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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/750,739	12/29/2000	Timothy J. Nichols	P-8863	7216

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MEDTRONIC, INC.
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EXAMINER

SUKHAPHADHANA, CHRISTOPHER T

ART UNIT PAPER NUMBER

2625

DATE MAILED: 03/17/2004

9

Please find below and/or attached an Office communication concerning this application or proceeding.

<p style="text-align: center;">Office Action Summary</p>	<p>Application No.</p> <p>09/750,739</p>	<p>Applicant(s)</p> <p>NICHOLS ET AL.</p>	
	<p>Examiner</p> <p>Christopher T. Sukhaphadhana</p>	<p>Art Unit</p> <p>2625</p>	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 December 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| <p>1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date <u>6,7</u>.</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6) <input type="checkbox"/> Other: _____.</p> |
|---|---|

DETAILED ACTION

Response to Amendment

1. The Preliminary Amendment filed 28 February 2001 has been entered in full.

Drawings

2. The drawings are objected to because there are handwritten characters in at least **Figs 3-**
5. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

3. The following quotation of 37 CFR 1.75(a) forms the basis of objection:

(a) The specification must conclude with a claim particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention or discovery.
4. **Claims 6 and 10** are objected to under 37 CFR 1.75(a) as failing to particularly point out and distinctly claim the subject matter which the applicant regards as his invention or discovery.
5. In regards to **claims 6**, the expression "iris/retina" can be interpreted as "iris and retina", "iris or retina", or "iris and/or retina", each of which define separate and distinct claim coverage. For the purposes of applying prior art, the Examiner will use the "iris or retina" interpretation.
6. In regards to **claim 10**, a similar argument as applied to claim 6 can be made.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. **Claims 1-9 and 11-13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith, Jr. et al (U.S. Patent 5,456,692, cited in IDS filed 15 April 2002, "Smith") in combination with Piosenka et al (U.S. Patent 4,993,068, newly cited, "Piosenka").

9. In regards to **claim 1**, Smith discloses a user recognition system (Fig 1) to identify a user and enable access to instruments associated with at least one implanted medical device, the system comprising: an implanted medical device (ref no 20, Fig 1, and col 11, line 30) in a patient; an instrument (col 11, line 31) in data communications with the implanted medical device; and a user recognition system (col 11, line 40) implemented in said instrument.

Smith does not expressly disclose the user recognition system submitting biometric traits of the user.

However, Smith discloses the user recognition system submitting a password, or series of passwords, that are known only to field clinical engineers, or others, who are authorized and have sufficient training to be able to replace the control program (col 11, lines 40-44).

Piosenka teaches a user recognition system (Fig 1) submitting biometric traits of the user.

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate Piosenka's submission of biometric traits in lieu of Smith's passwords because it provides a system that is not defeated by extracting "known" information (e.g. passwords) from

the rightful user allowing a fraudulent user to pose as the rightful user (Piosenka, col 1, lines 51-53, see also first two paragraphs of Summary of the Invention).

10. In regards to **claim 2**, Smith further discloses in col 11, line 30, said implanted medical device including a pacer.

11. In regards to **claim 3**, Smith further discloses in col 11, line 31, said instrument including a programmer.

12. In regards to **claim 4**, Piosenka further discloses in refs no 11-15, Fig 1, said user recognition system including a finger scanner, a camera, and a microphone.

13. In regards to **claim 5**, Piosenka further discloses in ref no 13, Fig 1, said biometric traits include a finger scan obtained from said finger scanner.

14. In regards to **claim 6**, Piosenka further discloses in ref no 12, Fig 1, said biometric traits include a retina scan obtained via said camera.

15. In regards to **claim 7**, Piosenka further discloses in ref no 14, Fig 1, said biometric traits including a voice print obtained from said microphone.

16. In regards to **claim 8**, Smith discloses a user authentication system (Fig 3) for identifying and granting access (ref no 301, Fig 3) to at least one user (col 11, lines 40-44) to an implanted medical device (col 11, line 31) in a patient associated with an instrument (ref no 46, Fig 1).

Smith does not expressly disclose the remaining limitations of the claim.

However, Smith discloses the user authentication system submitting a password, or series of passwords, that are known only to field clinical engineers, or others, who are authorized and have sufficient training to be able to replace the control program (col 11, lines 40-44).

Piosenka teaches a biometric-based user authentication system (Fig 1) for identifying and granting access to at least one user associated with an instrument (ref no 1, Fig 1), the authentication system comprising: at least one biometric sensor (ref no 11-15, Fig 1) implemented in the instrument; at least one biometric trait of a user stored as coded data (col 8, lines 10-32) in a memory bank of said biometric sensor; and means for analyzing and comparing (col 8, lines 33-68) said at least one biometric trait with said coded data to grant or deny access.

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate Piosenka's biometric-based user authentication system into Smith's external programmer 46 because it provides a system that is not defeated by extracting "known" information (e.g. passwords) from the rightful user allowing a fraudulent user to pose as the rightful user (Piosenka, col 1, lines 51-53, see also first two paragraphs of Summary of the Invention).

17. In regards to **claim 9**, Piosenka further discloses in refs no 11-15, Fig 1, said at least one biometric sensor including a camera, a finger print sensor, and a microphone.

18. In regards to **claim 11**, Smith further discloses in col 11, lines 28-44, said means for analyzing and comparing includes a software system implemented in the memory bank of the sensor.

19. In regards to **claim 12**, Smith further discloses in col 11, lines 44, "replace the control program", the biometric traits of the user stored as coded data includes instructions to allow a user with matching traits to have access to a pre-determined set of data and tools of said implanted medical device.

20. In regards to **claim 13**, Smith discloses a method for an identification system of a user (Fig 3) to provide authorized access (ref no 301, Fig 3) to operational hardware, software and patient medical data (ref no 301, Fig 3) contained in instruments and implanted medical devices (col 11, line 31).

Smith does not expressly disclose the remaining limitations of the claim.

Piosenka teaches a method for a biometric-based identification of a user (Fig 1) to provide authorized access, the method comprising: accepting at least one biometric trait from a potential user (ref no 11-15, Fig 1, and col 8, lines 33-47); comparing said at least one biometric trait to a stored coded data (col 8, lines 48-68); and granting a qualified access when a match is confirmed between said at least one biometric trait and the stored coded data (col 8, line 67).

21. **Claim 10** is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith, Jr. et al (U.S. Patent 5,456,692, "Smith") and Piosenka et al (U.S. Patent 4,993,068, "Piosenka") as applied to claim 8 above, in further combination with Clayden (U.S. Patent 5,787,185, newly cited, "Clayden").

22. In regards to **claim 10**, Piosenka further discloses said at least one biometric trait of a user including a fingerprint (ref no 13, Fig 1), a voice print (ref no 14, Fig 1), a retinal print (ref no 12, Fig 1), a facial model (facial photo, abstract), and a digital signature (ref no 15, Fig 1).

Smith and Piosenka do not expressly disclose including a veinal imprint.

Clayden teaches biometric identification using veinal imprint (col 2, lines 7-18).

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate Clayden's veinal imprint into Smith and Piosenka's system because Clayden's method is an improved method of verifying the identity of individuals (Clayden, col 1, line 33).

23. **Claims 14 and 15** are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith, Jr. et al (U.S. Patent 5,456,692, "Smith") and Piosenka et al (U.S. Patent 4,993,068, "Piosenka") as applied to claim 13 above, in further combination with Freed et al (U.S. Patent 6,132,363, newly cited, "Freed").

24. In regards to **claim 14**, Smith and Piosenka do not expressly disclose said qualified access including a hierarchical scheme to enable user-specific access and authorization based on expertise and need.

Freed teaches a qualified access including a hierarchical scheme to enable user-specific access and authorization based on expertise and need (col 12, lines 1-8, and paragraphs bridging col 12-13).

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate Freed's teachings into Smith and Piosenka's method because it insures security (Freed, col 11, line 63) and minimizes inadvertent changes to settings that should be factory adjustable only (Freed, col 12, line 7).

25. In regards to **claim 15**, Freed further discloses in the paragraphs bridging col 12-13, the hierarchical scheme including distinctions of access to various hardware, software tools to perform therapy, diagnose and monitoring functions designed to provide various levels of authorized access to physicians, nurses, technicians, patients, and their representatives.

Examiner's Comments

26. The Examiner wishes to point out that most of the preambles of Applicant's independent claims can be treated as "intended use" language, and thus would not ordinarily be granted any patentable weight in terms of applying prior art. However, Examiner has anticipated the event that Applicant chooses to reword the language of the claims to positively recite features in each of the preambles, and has applied the appropriate prior art above.

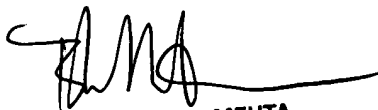
Conclusion

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher T. Sukhaphadhana whose telephone number is 703-306-4148. The examiner can normally be reached on 9a-4p M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bhavesh M. Mehta can be reached on (703) 308-5246. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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